

III. REMARKS

A. Amendments to the Claims

The amendments to claims 1-4, 6, 10 and 23-31 are made in response to the Examiner's rejection of claims 1-6, 8-13, 15-19 and 22-31 under 35 U.S.C. Section 112, second paragraph, and the reasons in support of that rejection.

Support for the amendment to claim 22 is provided by claim 23. The amendments to claims 5 and 30 are to cover a preferred embodiment disclosed in the Specification at page 7, lines 1-3. The amendments of claims 29 and 31 are to specific embodiments of the method set forth in claim 25.

Claim 3 has been amended to a method wherein the antimicrobial composition comprises propylene glycol and tannins. Support for this claim is provided in the Specification in Example 5, Disinfectant for Air Composition No. 10.

B. Rejection Under 35 U.S.C. Section 112

The Examiner has rejected claims 1-6, 8-13, 15-19 and 22-31 under 35 U.S.C. Section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The reasons for the rejection are set forth in the Action at page 2, line 15, to page 3, line 21. The amendments to the claims are intended to respond to the Examiner's Reasons for Rejection, except for claim 8, which has not been amended. Applicant believes that the phrase "from 0 to 99.8% by weight of propylene glycol" is supported by the Specification at page 6, lines 1-22. Accordingly, in view of the amendments to the claims, the rejection should be withdrawn.

C. Rejection Under 35 U.S.C. Section 103

1. Claims 1-6, 8-13, 15-19 and 22-31 are rejected under 35 U.S.C. Section 103 as being unpatentable over United States Patent No. 5,591,395 to Schroeder et al. ("Schroeder et al.") in view of United States Patent No. 5,569,461 to Andrews ("Andrews"), Scalbert et al. ("Antimicrobial Properties of Tannins,") *Phytochemistry* Vol. 30, No. 12, pp. 3875-3883, 1991 ("Scalbert et al."), Varga, J. (Derwent ACC-NO 1976-72203X (see Abstract) ("Varga Abstract"), United States Patent No. 4,110,430 to Hopp et al. ("Hopp et al."), United States Patent No. 6,033,705 to Isaacs ("Isaacs"), United States Patent No. 6,284,259 to Beerse et al. ("Beerse et al.") and United States Patent No. 6,086,904 to Crawford ("Crawford").

2. Examiner's Reasons in Support of the Rejection

The Examiner's reasons in support of the rejection are as follows:

[Applicant] claims a method for disinfection of air to reduce the concentration of germs comprising the distributing or atomizing of an antimicrobial composition wherein the antimicrobial composition is free from ethanol and isopropanol and wherein the antimicrobial composition comprises propylene glycol, tannins, lactic acid, benzyl alcohol and further comprises hydrocinnamic alcohol, additional GRAS flavoring agents such as essential oils (see, e.g. claims 10 and 31) and an emulsifier (see, e.g. claim 17).

Schroeder et al. teach a method of disinfecting the air to reduce germs (i.e., bacteria) contained within the air comprising distributing an antimicrobial composition comprising of propylene glycols in the air. Schroeder does not teach the other claimed active ingredient such as tannins, lactic acid, a benzyl alcohol, a hydrocinnamic alcohol, additional GRAS flavoring agents such as essential oils and an emulsifier contained within its antimicrobial composition to reduce germs such as microbials within the air.

Andrews teaches an antimicrobial composition comprising propylene glycol and lactic acid having antimicrobial activity (see, e.g., entire patent including claims and abstract).

Scalbert et al. beneficially teach (see, e.g. entire article) tannins to have antimicrobial properties.

Varga J beneficially teaches (see, e.g. abstract) a benzyl alcohol to have antimicrobial and/or antibacterial properties.

Hopp et al. beneficially teach (see, e.g., column 1, lines 21-29 and lines 60-65) a hydrocinnamic alcohol to have antimicrobial and/or antibacterial properties.

Isaacs beneficially [teaches] (see, e.g., column 10, lines 23-29) an emulsifier may be added to a compound to enhance its antimicrobial effect.

Beerse et al. beneficially teach (see, e.g. column 9, lines 19-39) essential oils (i.e. orange etc.) to have antimicrobial and/or antibacterial properties.

Crawford beneficially teaches that a composition comprising essential oils (i.e. orange) distributed within the air to disinfect the air (see, e.g. entire patent including abstract and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schroeder's antimicrobial composition comprising antimicrobial agents to be distributed with the air [sic] [to] disinfect the air to include the other claimed active ingredients having antimicrobial activity as beneficially taught by Andrew[s], Scalbert, Varga J, Hopp, Isaacs, Beerse and Crawford because the combined above references would create the claimed antimicrobial composition whereas when the claimed composition comprising of well known active ingredients having antimicrobial activity would intrinsically reduce when distributed within the air the composition of microbial and/or bacteria germs within the air. Furthermore, the adjustment of other conventional working conditions (e.g. the claimed concentrations of the antimicrobial compositions within the air, the type of antimicrobial system and/or spray design and the substitution of known bacteria for one another to be treated and/or reduced), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

(Action, page 4, line 15 to page 6, line 14).

**3. Legal standard
for rejections of claims under 35 U.S.C. Section 103**

The legal interpretation of Section 103 to be applied is set forth in the recent Supreme Court decision of *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. __, 82 USPQ2d 1385 (2007). KSR cites *Graham v. John Deere Co. of Kansas City*, (383 U.S. 1, 17-18 [148 USPQ 459] (1966)) as setting out an objective analysis for applying § 103. (82 USPQ 2d at 1388).

The objective analysis is as follows:

Under § 103, the scope and content of the prior art are to be determined; the differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

(148 USPQ at 467).

Accordingly, the factual inquiries set forth by the Court are as follows:

- [T]he scope and content of the prior art are . . . determined;
- Differences between the prior art and the claims at issue are . . . ascertained;
- The level of ordinary skill in the pertinent art [is] resolved; and
- Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized. . . .

The Supreme Court's analysis in *KSR* included a determination of obviousness based on the lack of improved results of a claimed combination over the elements in the combination. The Court cited *United States v. Adams*, 383 U.S. 39, 40 [148 USPQ 479] (1996) in determining that "The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art" (referring to *United States v. Adams*, 383 U.S. 39, 40 [148 USPQ 479] (1966) *Id.* 82 USPQ2d 1395).

4. Application of the Graham v. John Deere Co. factual standards

(a) Determining the scope and content of the prior art

Schroeder et al. discloses a method of disinfecting the air and killing airborne bacteria, etc. by creating particles of disinfecting compounds using a heated wick. As acknowledged by the Examiner, the Schroeder et al. composition comprises propylene glycol and not the combination of propylene glycol with tannins and/or lactic acid disclosed and claimed by Applicant. As discussed below, a low concentration of Applicant's claimed composition is due to the extraordinary effectiveness as an antimicrobial composition of a combination of propylene glycol and tannins and/or lactic acid. This extraordinary effectiveness is not shared by compositions comprising propylene glycol alone. Schroeder et al. does not disclose the concentrations in which the Schroeder et al. composition is used in air. However, given the much lower effectiveness of propylene glycol as an antimicrobial, the concentrations in air of the disinfecting compounds being employed by Schroeder et al. must be much higher than Applicant's claimed concentration.

Andrews is directed to a topical composition and related method for disinfecting, cleaning, conditioning and treating skin using a propylene glycol monoester and capric or caprylic acid, a second propylene glycol monoester of capric and/or caprylic acid, a synergist, propylene glycol, a surfactant and a vehicle (Abstract). The Andrews antimicrobial compositions are disclosed as useful when applied to the teats and udders of dairy animals as udder and teat washes and as pre-milking teat skin sanitizing solutions (pre-dips). (Column 2, lines 7-12). Accordingly, the Andrews compositions are used as a liquid. Andrews does not exemplify or otherwise disclose to one of ordinary skill in the art that the Andrews antimicrobial compositions can be employed in the air.

Scalbert reviews data on tannin toxicity against fungi, bacteria and yeasts and compared to toxicity of related lower molecular weight phenols (Abstract). Examples of tannin toxicity disclosed in Scalbert involve concentrations of tannin that are higher by many magnitudes than the concentration disclosed in Applicant's claims. In Scalbert, tannin concentrations vary from 0.063 gram per liter to 100 grams per liter. (See page 3878, lines 29-44 and page 3880, last paragraph). A concentration of 0.063 grams per liter, which is described in Scalbert as "a low tannin concentration" is equivalent to a concentration of about 1 part per 16,000 parts of composition. In contrast, Applicant's claims are limited to concentrations in air of from 5 to 10 parts per billion, or about 6,000 times lower than the lowest tannin concentration disclosed in Scalbert. From the range of concentrations given for tannins in Scalbert and the expression of concentration in grams per liter, it appears that the Scalbert composition is in liquid form and not intended to be used in air. As noted above, Scalbert does not disclose any concentrations in air at which the Scalbert composition is intended to exist, let alone the concentrations of antimicrobial composition in the air set forth in Applicant's claimed method.

The Varga Abstract discloses treatment of the surface of a doormat with the combination of methylparaben, propylparaben and benzyl alcohol to disinfect it and destroy bacteria, fungi, and viruses deposited on the mat. It appears that the Varga composition is in liquid form and is not intended to be present in the air. Varga does not disclose any concentrations in air at which the Varga composition is intended to exist, let alone the concentrations of antimicrobial composition in the air set forth in Applicant's claimed method.

Hopp et al. is directed to a germ-inhibiting, microbicidal or deodorizing composition comprising p-isopropyl-and/or p-tert.butyl-alpha-methyl hydrocinnamic alcohol, together with a carrier or dilutant (Abstract). The Hopp et al. composition appears to be in the form of a liquid or spray. Hopp et al. discloses that "the germ-inhibiting microbicidal properties of the hydrocinnamic alcohols to be used according to the invention become apparent when these compounds are applied in an amount of at least 0.001 mg per cm² of skin. (Column 1 lines 61-64). Such concentrations appear to be several orders of magnitude greater than the concentration of antimicrobial composition in air set forth in Applicant's claimed method. No other concentrations of the composition are disclosed.

Isaacs and Beerse et al. relate to treatments of a surface with an antimicrobial liquid. Isaacs is directed to a process for inhibiting microbial growth on a surface of an edible foodstuff, which comprises applying to the surface a defined compound selected from a group consisting of certain fatty acids and derivatives of fatty acids and fatty alcohols (Abstract). Beerse et al. relates to an antimicrobial wipe comprising a porous or absorbent sheet impregnated with an antimicrobial cleansing composition, wherein the antimicrobial cleansing composition comprises from about 0.001% to about 5.0% by weight of the antimicrobial cleansing composition of an antimicrobial active. Neither Isaacs nor Beerse et al. discloses a method which involves the achievement of a concentration in air of from 5 to 10 parts per billion of the antimicrobial composition.

Crawford discloses a solid composition including a gum material and a tea tree oil, and optionally another essential oil wherein the solid composition releases vapor containing the essential oil when exposed to an effective flow of gas. A method of diffusing tea tree oil into the atmosphere and a method of disinfecting air conditioning systems are also provided (Abstract). The composition preferably includes a gum material (Col. 2, lines 33-36). Examples of essential oils exhibiting antimicrobial activity include oils from oranges (Col. 3, lines 12-17). The essential oil may be solubilized with propylene glycol (Col. 3, lines 54-57). Crawford does not disclose Applicant's claimed method which employs very low concentrations of air or Applicant's antimicrobial compositions.

**(b) Ascertaining the differences
between the prior art and the claims at issue**

Independent claims 1 and 22 are directed to a method and composition for the disinfection of air comprising the distributing or atomizing of an antimicrobial composition that can be added to the air to achieve a dosage of from 0.001 to 1 ml per cubic meter of air per hour. The claims also are directed to the achievement of a permanent concentration of from 5 to 10 ppb (parts per billion) of the antimicrobial composition in the air. The antimicrobial composition is free from ethanol and isopropanol and comprises propylene glycol and at least one flavoring agent selected from tannins and lactic acid. Independent claims 23, 25 and 27 are also directed to the above-referenced method, except that disinfection of air is further defined as reducing the concentration of germs selected from gram-positive bacteria, gram-negative bacteria, molds, spore-formers, viruses, *bacillus subtilis*, *pseudomona fluorescens*, *staphylococcus aureus*, *aspergillus niger*, *hepatitis B* and *bacillus anthracis*. The remaining claims 2-6, 8-13, 15-19, 24, 26 and 28-31 are dependent upon the above-referenced independent claims or are dependent upon a claim that in turn is dependent upon one of the above-referenced independent claims.

Claim 3 has been amended to a method wherein the antimicrobial composition comprises propylene glycol and tannin. As discussed below, the composition comprising propylene glycol and tannin is unexpectedly more effective by several orders of magnitude as an antimicrobial agent than propylene glycol or tannin alone.

The prior art references, when combined, do not teach or suggest all of Applicant's claimed limitations, in particular, Applicant's claimed microbial composition comprising propylene glycol in combination with tannins (*i.e.*, tannic acid) and/or lactic acid and a concentration in air of from five to ten parts per billion of the antimicrobial composition. Instead, the prior art relied on by the Examiner employs compositions that do not disclose propylene glycol in specific combination with tannins and/or lactic acid. In addition, the concentrations of the prior art compositions are many orders of magnitude greater than Applicant's claimed composition. Accordingly, the prior art does not satisfy the criteria that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art.

The Examiner suggests that the modification of the prior art is merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. In fact, the prior art relied on by the Examiner cannot be so modified. As noted above, Scalbert discloses a range of concentrations of tannins over 6,000 times the concentration of the composition set forth in Applicant's claims. The Scalbert article focuses on tannin toxicity and the concentration of tannins required to achieve toxicity for fungi, bacteria and yeasts. The Scalbert article discloses that even at one hundred grams per liter, certain species of *penicillium* and *aspergillus* still achieve good growth (p. 3880). This disclosure suggests that the much lower concentrations of tannins set forth in Applicant's claims would be less effective, not more. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In addition, as noted above, Scalbert and several other references relied on by the Examiner are not directed to a method using antimicrobial compositions in very low concentrations in air. Indeed, the concentrations proposed in Scalbert are not applicable to a method of disinfection in air. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

For the reasons set forth above, one skilled in the art cannot derive from the combination of references relied on by the Examiner how to obtain Applicant's claimed method.

(c) Resolving level of ordinary skill in the pertinent art

The inventor of the present application, the inventors of the prior art patents and the authors of the prior art publications represent persons of ordinary skill in the art.

(d) Possible utilization of secondary considerations

There has been a long felt need to disinfect the air by means of the distribution/atomization of an antimicrobial composition that is surprisingly effective at very low concentrations so as not to otherwise affect the environment in which the composition is present.

**5. Application of the KSR Test
to determine whether claimed method is unobvious**

As noted above, the Supreme Court in *KSR* reaffirmed the precedent for determining obviousness of a combination set forth "in *Anderson's-Black Rock, Inc. v Pavement Salvage Co.*, ... [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation." *Id.* at __, 82 USPQ2d at 1395.

Accordingly, applying the *KSR* test, Applicant's claimed method of disinfection of air using a composition comprising propylene glycol and tannins must disinfect the air more effectively than a composition comprising one of propylene glycol or tannin.

**6. Applicant's claimed method produces
unexpectedly superior results in disinfecting air**

As set forth in the Specification in Example 5 at page 28, line 11, to page 33, line 12, comparative compositions comprising 100% propylene glycol and 100% tannin were tested against compositions of the invention comprising mixtures of at least two of propylene, glycol, tannin and lactic acid. The comparative and inventive compositions were each given a Disinfection Agent for Air (DOA) composition number. The DOA numbers for the comparative and claimed compositions including the components of the claimed compositions are given in the TABLE at page 31 and are identified below:

DOA Number	Status	Composition
1	Comparative	100 propylene glycol
5	Comparative	100 tannin
10	Claimed	92 propylene glycol 5 benzyl alcohol
12	Claimed	91 propylene glycol 5 benzyl alcohol 3 tannin 1 orange
14	Claimed	91 propylene glycol 5 benzyl alcohol 3 tannin 1 lemon grass
16	Claimed	97 propylene glycol 3 tannin
18	Claimed	97 benzyl alcohol 3 tannin
20	Claimed	90 propylene glycol 5 benzyl alcohol 3 tannin 1 lactic acid

As noted at page 28, line 19, the dosage was 0.05 ml per m³ of air (1-10 ppb — parts per billion). The air being treated contained a starting suspension of germs comprising 8.7 x 10⁸ *bacillus subtilis* (ATCC), 5.1 x 10⁸ *staphylococcus aureus* (ATCC), 4.4 x 10⁸ *pseudomonas fluorescens* (ATCC), 3.8 x 10⁸ *aspergillus niger* (ATCC) and 2.0 x 10⁶ *hepatitis B* (HBsAg). (See page 32, under TABLE 5).

As shown in TABLE 5 at page 32, treatment with the dosages comprising the comparative compositions of 100% propylene glycol (DOA No. 1) and 100% tannin (DOA No. 5) resulted in no reduction in the germ concentration. However, treatment with the dosages comprising each of the claimed compositions (DOA Nos. 10, 12, 14, 16, 18 and 20) resulted for each of the claimed compositions in a germ reduction of 10⁴ to 10¹/m³.

The results obtained in the test program described in the Specification under Example 5 are consistent. At the concentrations of the antimicrobial composition employed in Applicant's claimed method, the starting ingredients disclosed in the prior art (propylene glycol or tannin) are generally ineffective. Applicant's claimed method employs these ineffective starting ingredients together to create an antimicrobial composition that is unexpectedly and strikingly more effective in lowering the concentrations of microbes. As noted above, the Supreme Court's analysis of KSR included the following test to determine the obviousness or unobviousness of Applicant's claimed method:

The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art" (referring to *United States v. Adams*, 383 U.S. 39, 40 [148 USPQ 479] (1966) *Id.* 82 USPQ2d 1395 (2007)).

Accordingly, using the Supreme Court's current test for obviousness or unobviousness of claims under 35 U.S.C. Section 103, Applicant's claims are unobvious over the prior art cited by the Examiner in this rejection.

Applicant's claimed antimicrobial composition, as set forth in particular in claim 3, which comprises propylene glycol in combination with tannin (*i.e.*, tannic acid), is unexpectedly superior as an antimicrobial composition than propylene glycol or tannin alone. The superiority of Applicant's DOA Number 20 composition which comprises propylene glycol, tannin and lactic acid compared with compositions comprising propylene glycol or tannin alone further supports the patentability of Applicant's claimed method, which comprises compositions of propylene glycol and tannin and/or lactic acid. Because of this unexpected superiority, Applicant's claimed method can utilize an antimicrobial composition in extremely low concentrations in air, namely, 5 to 10 parts per billion. None of the prior art references relied on by the Examiner discloses, exemplifies or even suggests to one of ordinary skill in the art a method using antimicrobial compositions in such low concentrations.

Accordingly, the rejection of claims 1-6, 8-13, 15-19 and 22-31 under 35 U.S.C. Section 103 as being unpatentable over the combination of the eight prior art references identified by the Examiner is untenable and should be withdrawn.

IV. Conclusion

It is believed that the above Amendment and Remarks constitute a complete response under 37 CFR §1.111 and that all bases of rejection in the Examiner's Action have been adequately rebutted or overcome. A Notice of Allowance in the next Office Action is, therefore, respectfully requested. The Examiner is requested to telephone the undersigned attorney if any matter that can be expected to be resolved in a telephone interview is believed to impede the allowance of pending claims 1-6, 8-13, 15-19 and 22-31 of United States Patent Application Serial No. 10/019,240.

Respectfully submitted,

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